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K011917

10.0 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR 807.92.

Contact Person:	James P. Raskob GE Lunar Corporation 726 Heartland Trail Madison, WI 53717
Phone:	(608) 826-7425
Fax:	(608) 826-7107
Date:	June 19th , 2001
Device/Trade Name:	Advanced Hip Assessment Software Option
Common Name:	Bone Densitometer
Classification Name:	Bone Densitometer 21CFR 892.1170
Predicate Devices:	LUNAR EXPERT Morphometry Software 510(k) K950611 LUNAR EXPERT Spine Morphometry Reference Values 510(k) Number K961007

10.1 DESCRIPTION OF THE DEVICE:

The Hip Morphometry Software, to be marketed as Advanced Hip Assessment Software, analyzes previously acquired dual-energy x-ray absorptiometry (DEXA) images of the proximal femur from the Prodigy bone densitometer for measurement of the hip axis length (HAL). The patient is scanned for bone density of the proximal femur with the currently distributed product, and the Hip Morphometry Software measures the HAL. A mean value of HAL for Caucasian females is included for comparison at the sole discretion of a physician.

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10.2 CONCLUSION

The Hip Morphometry Software is substantially equivalent to currently marketed software. No new safety and effectiveness questions are raised with the Hip Morphometry Software application.

James P. Raskob
Signed

James P. Raskob
Printed Name

Regulatory Affairs/Quality Assurance Manager
Title

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 3 2001

Mr. James P. Raskob
Regulatory Affairs & Quality Assurance Manager
GE Lunar Corporation
726 Heartland Trail
MADISON WI 53717

Re: K011917
Advanced Hip Assessment Software
Dated: June 19, 2001
Received: June 20, 2001
Regulatory Class: II
21 CFR 892.1170/Procode: 90 KGI

Dear Mr. Raskob:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

K011917

3.0 INDICATION FOR USE FORM

- 510(k) Number (if known) K011917
- Device Name: Hip Morphometry Software
- Market Name: Advanced Hip Assessment
- Indications for use:

Hip Morphometry Software option is used on a typical dual-energy x-ray absorptiometry (DEXA) image of a femur from a Prodigy bone densitometer. This software provides a measurement of the hip axis length (HAL) and a mean value of HAL for Caucasian females.

The use of the Prodigy bone densitometer is restricted to prescription use only. The operator's manual for these products contains the following statement:

> "United States Federal Law restricts this device to the sale, distribution, and use by or on the order of a physician."

PLEASE DO NOT WRITE BELOW THIS LINE. CONTINUE ON ANOTHER PAGE IF NEEDED.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K011917